

REGISTRATION

2724-796

Vol.1

DATA PACKAGE BEAN SHEET

Date: 20-Jul-2011

Page 1 of 3

Decision #: 450779

DP #: (392061)

PRIA

Parent DP #:

Submission #: 898012

E-Sub #:

*** Registration Information ***

Registration: 2724-796 - RF 2042 (CDSO)

Company: 2724 - WELLMARK INTERNATIONAL

Risk Manager: RM t3 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Kevin Sweeney KSWEENEY

Sent Date: _____

Calculated Due Date: 12-Nov-2011

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R340) NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL STATEME

Ingredients: See page 3

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 20-Jul-2011

Due Back: _____

DP Ingredient: See page 3

DP Title: _____

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 13-Oct-2011

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Byron,

Please find attached the Wellmark response to your review regarding CAS for puppies for 2724-796. These data are also cited for 2724-811, which is attached.

The registrant originally submitted this response and it got coded as a 570. They are now submitting as a R340 under PRIA.

Kevin
305-5063

DP#: (392061)

*** Studies Sent for Review ***

Decision#: (450779)

MRID	MRID Status	Citation Reference	Guideline
48511701		Petree, L.; McFadden, J. (2011) Analysis of Adverse Effect Incident Data for RF2042 [CDSO]. Project Number: 4043. Unpublished study prepared by Wellmark International. 22 p.	

DP#: (392061)

*** Product Data Package Ingredients ***

Decision#: (450779)

PC Code	CAS	Ingredient Name
067501	51-03-6	Piperonyl butoxide
105402	65733-16-6	S-Methoprene
128965	80844-07-1	Ethofenprox
067501	51-03-6	Piperonyl butoxide(5%)
105402	65733-16-6	S-Methoprene(3.6%)
128965	80844-07-1	Ethofenprox(30%)

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: SEP - 1 2009		EPA Reg. Number: 2724-796		
	Check List Item	Yes	No	N/A
1	Has the PRIA Fee been Paid ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an Application Form (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a Confidential Statement of Formula (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?		X	
4	Is a Formulator's Exemption Statement (EPA Form 8570-27) Included in the Submission Package?		X	
5	Is a Certification with Respect to Citation of Data (EPA Form 8570-34) Included in the Submission Package?		X	
6	Is a Data Matrix (EPA Form 8570-35) Included in the Submission Package?		X	
7	Is a Label Included in the Submission Package?	X		
8	Are Data Included in the Submission Package?	X		
9	Is the Submission an Amendment ?	X		

REGULATORY LABEL DATA SHEET

File Name: Epa amend add puppies enhanced 311 **Data Sheet Date:** June 2011
Product: RF2042 [CDSO] **EPA Reg #:** 2724- 796
Approved: **Supersedes:** 1/19/10

OVERVIEW: Label amendment to add use on puppies 10 weeks of age or older plus add topical risk mitigation text

Page #	Description of Major Changes
1	Added "For Use only..." and "Do not use on cats" to front panel per risk mitigation text Marketing claims: added Puppies Added "Controls fleas, ticks and mosquitoes for up to one month" and "Monthly treatment for control of fleas, ticks and mosquitoes" Ingredient Statement – deleted option of back panel placement revised PBO reference per DCI Net Contents – added fl oz as main net contents expression
2-3	Added risk mitigation text and added puppy use Added Use Restrictions per PBO DCI
4	Precautionary Statements – added puppies Added risk mitigation text Added text to be included on individual applicator

RF2042 [CDSO]

Front panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Front panel – **!CON - DO NOT USE ON CATS!**

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs & Puppies 10 weeks 6-months of age or older]

Effective on indoor and outdoor dogs/puppies

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's/puppy's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS:..... 61.4%

TOTAL 100.0%

*Equivalent to minimum 4.00% (butylcarbityl) (6-propylpiperonyl ether) and 4.00%-related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz/(1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS/PUPPIES LESS THAN 10 WEEKS 6 MONTHS of AGE or LESS

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS!

[Back panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] ~~should be applied~~ evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

[Alternate Directions for Use for multi-tube application

- 3 The dog/puppy should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on ~~pets~~ dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of ~~pets~~ dogs/puppies with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If **empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 6 MONTHS/10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173
[URL]
Made in USA

TEXT FOR INDIVIDUAL APPLICATOR

Product name
Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%
KEEP OUT OF REACH OF CHILDREN
CAUTION
READ DIRECTIONS BEFORE USING
EPA Reg No.
Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Decision Information for 2724-796

Decision Seq: 450779 Action Code: R340, NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTION) ...

FFS Start Date: 12-Jul-2011 Tentative Ind: No FFS Original Decision: ...

Due Date: 12-Nov-2011 75-Day Due Date: ... FFS EUP Decision: ...

OPP Target Due Dt: ... 21-Day Screen Dt: 12-Jul-2011 FFS Primary Decision: ...

Negotiated Due Dt: ... Start/Stop Clock: FQPA Clock: ...

Registrant: Response Due Date: Days Elapsed: ...

Current Status: PENDING (21-Jun-2011)

Decision Status

Tracking

Create Resubmission

FFS Letters

Action Code History

Secondary Decision

Decision Comments Payment Unmatched Payments 75 Day Letters

Meetings & Milestones FFS Information FFS Negotiated Due Dates OPP Target Due Date

Decision Ownership Receipts Data Package Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S 898012	Sweeney, Kevin	2724-796	12-Nov-2011	PENDING

Label Amendment

Viewing Record 1 of 1

Receipt for Section 3

S: 898012

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 2724 WELLMARK INTERNATIONAL

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 2724-796 Product Name: RF 2042 (CDSO)

Override#

Me Too

Section3

Me Too

Product Name:

Application Date: 14-Jun-2011



OPP Rec'd Date: 17-Jun-2011



Front End Date: 20-Jun-2011



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2402 (CDSO)	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 150 t East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Enclosed please find materials to support a label amendment intended to add puppies to the label for this product. We are submitting one study, and the data will be reviewed in RD, not in other divisions. We therefore expect this action to be assigned to PRIA Category R340. A check for \$357 has been sent to the appropriate government lockbox in St. Louis. For questions, contact: James McFadden; Tel: (847) 330-5305; Fax: (847) 330-5369; E-Mail: jmcadden@central.com

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted If "Yes" Unit Packaging wgt. No. per container t. 5/3/4.5/6/9 cc t. 3,6		If "Yes" Unit Packaging wgt. No. per container _____			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.5/3/4.5/6/9 cc applicators		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed on cardboard or carton			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James McFadden	Title Sr. Regulatory Project Manager	Telephone No. (Include Area Code) (847) 330-5369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 		3. Title Sr. Regulatory Project Manager
4. Typed Name James McFadden		5. Date June 14, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 28, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAMES MCFADDEN, PH.D.
WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 17-JUN-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 898013

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 2724 WELLMARK INTERNATIONAL V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 2724-811 Product Name: RF2164 A/T COMBO

Overrides:

Me Too Section3: Me Too Product Name:

Application Date: 14-Jun-2011

OPP Rec'd Date: 17-Jun-2011

Front End Date: 20-Jun-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

Form A: ☐

Signature Date:

Form B: ☐

New Ingredient

Request Date:

New Ingredient

Received Date:

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

Receipt for Section 3

S: 898012

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 2724 WELLMARK INTERNATIONAL

V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 2724-796 Product Name: RF 2042 (CDSO)

Override:

Me Too

Me Too

Section3:

Product Name:

Application Date: 14-Jun-2011

OPP Rec'd Date: 17-Jun-2011

Front End Date: 20-Jun-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit

New Ingredient

Request Date:

New Ingredient

Received Date:

Wellmark™

*This package contains
two amendments that
represent a primary &
secondary submission
2724-796 - primary, with data
2724-811 - secondary, depends
on some data*

NR 485117-00

James McFadden, Ph.D.
Sr. Regulatory Project Manager

Wellmark International
1501 E. Woodfield Rd
Suits 200W
Schaumburg, IL 60173

847-330-5368 phone
847-330-5391 fax

jmcadden@central.com
www.centrallifesciences.com

June 14, 2011

Richard Gebken, PM 13
Registration Division (AMEND)
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

**Subject: Submission of Label Amendment for a Product Containing Etofenprox:
EPA Reg. No. 2724-811; RF2164 A/T COMBO**

Dear Mr. Gebken:

Enclosed with this letter please find material to support a label amendment for Wellmark International's product RF2164 A/T COMBO (EPA Reg. No. 2724-811). The purpose of this amendment is to add uses on puppies to the existing label. We are also making a minor revision to the statement regarding potential adverse effects.

The basis for this amendment, however, is discussed at length in a concurrently submitted label amendment for a related product, Wellmark EPA Reg. No. 2724-796, the RF2042 [CDSO]. That submission includes an additional report for review, revised data matrix, etc.

The label amendment for the 2724-811, RF2164 A/T COMBO depends entirely on the data submitted with that application. Therefore, as far as we understand, this application (for 2724-811) should be classified as a secondary submission under PRIA category R340.1, since we expect the other submission to be R340, and is the primary submission. A check in the amount of \$904.25 (1/4th of the PRIA R340 fee) has been submitted to the government lockbox in St. Louis, and a copy is enclosed with this submission.

Because supporting material was included with the submission for 2724-796, this application for a label amendment contains only:

Form 8570-1, Application for label amendment
Revised label (5 copies)

Please let me know if you have questions or need more information regarding this submission.

Regards,



James McFadden, Ph.D
Sr. Regulatory Project Manager

Memorandum

Date: 6 / 28 / 11

To: PM 13, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 7-8-11

Document Part Of: 2724-796
MRID, If Any: 485117

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Overall Status: Pass/Fail

Document returned to:

Stephen Schable

PM 13

y

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 6-17-11

Experts In-Processing Signature: MF Harrington Date 6-21-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2724-796</u>		EPA Receipt Date: <u>6-17-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

The study was initially rejected (based on 86-S review) because a supplemental claim of confidentiality was erroneously claimed on the basis of FIFRA 10(d). The registrant was contacted 6/24/11 and sent corrections accordingly.

6/28/11
KCN

Ticket passed

Studies passed 86-S review MRID 485117

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/opbhppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 21, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-450779
EPA File Symbol or Registration Number: 2724-796
Product Name: RF 2042 (CDSO)
EPA Receipt Date: 17-Jun-2011
EPA Company Number: 2724
Company Name: WELLMARK INTERNATIONAL

JAMES MCFADDEN, PH.D.
WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to read "M. J. Li", is written over the typed name.

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

my
{898012A~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S-

898012

EPA File Symbol/Reg. No.

2724-796

Pin-Punch Date:

6/17/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R340

Granted: R340

Amount Due: \$ 3,617. ⁰⁰

Parent/Child Decisions:

parent 2724-796

child 2724-811

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: 

Date: 6-21-11

Remarks:

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

Wellmark International
1501 E. Woodfield Road
Suite 200 West
Schaumburg, IL 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Report Submission to Support Label Amendment to add Use on Puppies to Label
Product Name: RF2042 [CDSO]; EPA Reg. No. 2724-796

3. TRANSMITTAL DATE

June 14, 2011

4. LIST OF DOCUMENTS SUBMITTED

1. Petree, L. and McFadden, J. (2011) Analysis of Adverse Effect Incident Data for RF2042 [CDSO], EPA Reg. No. 2724-796, unpublished, Wellmark International Study No. 4043, 22 pp.

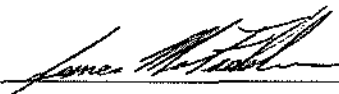
5. COMPANY NAME

Wellmark International

6. COMPANY AGENT

James McFadden
Sr. Regulatory Project Manager
Wellmark International
1501 E. Woodfield Rd., Suite 200 West
Schaumburg, IL 60173

7. AGENT SIGNATURE



DATE: June 14, 2011

8. COMPANY CONTACT: James McFadden PHONE: 847-330-5369

Wellmark International

1501 E. Woodfield Rd
Suite 200W
Schaumburg, IL 60173

847-330-5388 phone
847-330-5391 fax

jmfadden@central.com
www.centrallifesciences.com

June 14, 2011

Richard Gebken, PM 13
Registration Division
Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

Subject: Submission of Label Amendment for a Product Containing etofenprox:
EPA Reg. No. 2724-796; RF2042 (CDSO)
Contains Confidential Business Information (Discussion of Inert Ingredients)

Dear Mr. Gebken:

Enclosed with this letter please find material to support a label amendment for Wellmark International's product RF2042 (CDSO) (EPA Reg. No. 2724-796). The purpose of this amendment is to add uses on puppies back to the existing label. After the RF2042 (CDSO) was registered, (3/10/2009) the companion animal safety study for puppies was rejected, (MRID 47622203, DP Barcode DP 360171) forcing us to delete that use from the product label.

Since the initial rejection of that study, Wellmark has made several attempts to get puppies added back to the label. Wellmark submitted a report amendment (MRID 47835301, 8/24/09) that addresses issues identified by the Technical Review Branch (TRB) in the review for the original puppy companion animal safety study; the issue has also been discussed in other letters and in a meeting with EPA in January of 2010.

This submission collects the arguments submitted previously, provides an additional report as supporting data, and ties all of this to a request to approve specific label language submitted with this label amendment.

Because this submission will not require review outside of RD, we expect the submission will be classified as PRIA category R340, and will have a 4-month review time. PRIA category R340 has a PRIA fee of \$3617, and a check for that amount (copy enclosed) has been submitted to the designated government lockbox in St. Louis.

The application for label amendment includes the following components:

- Form 8570-1, Application for label amendment
- Revised label (5 copies)
- Form 8570-34, Certification with Respect to Citations of Data
- Form 8570-35, Revised Data Matrix
- Transmittal Document for one study submitted with this application

The following paragraphs discuss this submission in more detail:

Background for the Amendment

In order to understand the background for this amendment, we first provide a summary of recent regulatory actions related to this product. Essentially, the reviews that EPA has provided for previous actions constitute the background for evaluation of this amendment.

Date	Action/Issue	Data
3/10/2009	Notice of Registration	Original submission
6/04/2009	Amend to Remove Puppies, CAS Study rejected (study orig. submitted with 2724-797)	MRID 47622203, DP 360171 (dated 5/22/2009)
8/24/2009	CAS Report Amendment, DER Rebuttal submitted, non-PRIA	MRID 47835301
8/31/2009	Label Amendment for safety to cats and changes in dose groups (4 → 5)	Reference to MRID 46513409, (CAS in cats), MRID 47844001
1/19/2010	Amendment to change dose groups approved, safety to cats not approved	DP 369326, 12/09/2009
1/28/2010	Meeting with EPA to discuss pet issues and MRID 47835301, EPA recommended submission of a PRIA action.	
2/24/2010	Amendment to add puppies and kittens to <u>pet spray</u> submitted, also requested review for 2724-796	DP376421, 6/23/2010 (review did not consider 2724-796)

CAS = Companion Animal Safety

From DP 360171, 5/22/2009, where EPA rejected the puppy companion animal safety study:

TRB's primary concern is that adverse effects - even though they could be considered as minor (loose feces and vomiting) - occurred following IX exposure (use application rate) to the test material. Considering that only 12 puppies were tested at 1 X, the occurrence of effects in two indicates a high potential for adverse incidents - including some of greater severity - if the formulation is registered for use as a spot-on for puppies. Even if nothing abnormal had been observed at IX, the occurrence of adverse effects at 3X (one male had a bloody fecal discharge and vomiting on Day 1, and loose stools on Days 2 and 3; another male had vomiting on Day 1) would indicate a less than 3X margin of safety for this use on puppies. Since there is an inadequate margin of safety, the study is classified as unacceptable and cannot be used to support the use of this formulation as a spot-on for puppies.

From DP 369326, 12/09/2009, where EPA raised additional concerns about the dog topical:

2. Although the material in MRID 478440Q1 references studies on cats and kittens conducted With etofenprox -containing formulations in which no significant adverse effects were observed, the Agency has received incident reports for both the primary registration (2724-504) and distributor products (2724-504-270 and 2724-504-2S96) of a 40% Etofenprox and 3.6% S-methoprene containing formulation. These incidents include a total (for 2008) of 82 deaths (by all exposure routes) in cats or kittens. In addition, the presence of lanolin in 2724-796 creates a potential problem, as some cats (particularly Siamese) may be attracted to lanolin (see <http://www.messybeast.com/pica.htm>). and may go out of their way to lick lanolin-treated items. It is also noted that 2724-504 does not contain

piperonyl butoxide, which is present in 2724-796 and which could enhance the toxicity of the etofenprox to the cat. Based on these considerations TRB recommends against any statement indicating that accidental exposure to cats from treated dogs will not cause serious harmful effects.

3. Based on the incident reports for EPA Reg. No. 2724-504 and the attractiveness of lanolin to some cats, TRB strongly recommends that lanolin be removed from 2724-796. Otherwise some cats in multiple-pet households will ingest this product by licking or grooming the dog's treated coat.

From: DP376421, 6/23/2010, where EPA accepted adding puppies to the spray, but did not address the spot on:

Based on the low number and transient nature of effects observed at IX in the spot-on puppy study (one incident of loose stools on Day 3 and one incident of vomiting after the second dose) in conjunction with the reduced exposure to actives, TRB concludes that this study is acceptable to support a spray-on use of 2724-797 at an application rate of 8 g/kg or lower to puppies of 10 weeks of age and older.

In these reviews, even the most recent, the EPA has not directly addressed the statistical arguments that were presented in the 8/24/2009 rebuttal to the DER (MRID 47835301). Wellmark believes that this is a key issue – the basic argument is that the observed “effects” were determined to be not statistically significant in the 1X and 3X dose groups (Hansen, 2009). Observations in the 5X group occurred at rates similar to adverse events in 1X applications of registered products. In addition, potential concerns related to attractiveness to cats appear to be anecdotal, and not legitimate.

Review of the clinical observations show that in Group A only two females had clinical signs. One with loose stools several days after the first dose, an observation also noted a few days before initiation of test material administration for this animal. And, a single observation of vomit was recorded in one female Day 9. Since both loose stools and vomit are common clinical observations in laboratory puppies, the significance of these observations was further investigated. APSS scientists reviewed the clinical observations reported in the study. The evaluation included statistical analysis of the gastrointestinal signs in this study and a review of the incidence of gastrointestinal signs in the APSS public adverse reaction database. The statistical evaluation showed that the increase in gastrointestinal signs was statistically different from the controls only at the 5X dose and that the occurrence of these signs at the 5X dose were similar to what is reported to ASPCA leading to the conclusion that (Hansen 2009) “The occurrence of mild gastrointestinal signs following high dose (5X) exposure to JM982 spot-on in puppies is similar to reported signs following appropriate use (1X) of EPA registered and currently marketed spot-on formulations containing active ingredients other than etofenprox”.

Based on analysis of the adverse reaction type and frequency reported to the ASPCA, occasional gastrointestinal signs are a common complaint (19.1% of total) in currently registered products. Since statistically significant effects compared to controls occurred only at the 5X level and not at 1X or 3X, and the effects seen at 5X are similar to current products, it is expected that the product(s) supported by this study do have an acceptable margin of safety.

In summary, in 2009 Wellmark provided (DER) rebuttal arguments to EPA that have not been thoroughly evaluated (as far as we understand). In addition, reviews provided by EPA contain material (suggestions of potential risk due to lanolin¹) do not appear to be adequately supported. This current submission for a label amendment requests re-evaluation of previously submitted data, as well as evaluation of a new study which reaches similar conclusions.

¹ In addition, the properties of raw lanolin may be very different from the properties of the material used as an inert ingredient in the formula for 2724-796.

Content of This Submission:

With this proposed label amendment, Wellmark is submitting a review of adverse incident data (Petree and McFadden, 2011) for the 2724-796 product; including adverse events due to misapplication to puppies. If the EPA's conclusions in DP 360171 (5/22/2009) are correct, adverse events in puppies should show an increased rate of incidents with gastrointestinal signs.

Instead, the review of Adverse Effect Incidents provided with this submission finds that:

- The distribution of severity of adverse events in puppies (due to misapplication) for the etofenprox product was better than for a permethrin product that allows applications to puppies.
- No elevation of digestive system events in puppies was found for the etofenprox product when compared to two permethrin dog topicals.
- Instead, the distribution of mild clinical signs for puppies for the etofenprox product was found to be similar (not statistically different from) the distribution of mild clinical signs in adult dogs.

The review of adverse effect incident data shows conclusively that there is no safety hazard associated with the use of the etofenprox topical product on puppies. Even though the current label does not permit application to puppies, events due to misapplication provide a more than sufficient foundation for analysis.

Overall, the incident data available to Wellmark International and reviewed in this report are the equivalent of a very large scale performance monitoring study. Millions of product doses were sold, and even though the total number of applications to puppies is unknown, this analysis represents a much larger sample than one could obtain even in any clinical study.

Notably, the summary conclusion of this analysis of incident data is similar to that reached in the Hansen (2009) report (in MRID 47835301): (1) there is no evidence of a higher frequency of adverse events with gastrointestinal signs and (2) the etofenprox product appears to have an acceptable margin of safety. In addition, this new analysis documents that the etofenprox spot on has at least three significant benefits for the etofenprox spot on product compared to the permethrin product:

- The total rate of adverse incidents was lower
- The rate of incidents in cats was much lower
- The rate of incidents in small dogs (< 15 lbs.) was lower, suggesting that small dogs that were particularly sensitive to permethrin were less sensitive to etofenprox.

Thus, in addition to documenting that there is an acceptable margin of safety in puppies, the analysis of incident data documents that the etofenprox product has an improved safety profile compared to permethrin products. Because of this improved safety profile, Wellmark believes that some form of label language reflecting these facts should be permitted by EPA, since it is in the best interests of the EPA to allow consumers to make an educated choice. (Previous attempts to address this issue have been rejected by EPA.)

Specific Changes Proposed in the Label Amendment

To highlight specific changes proposed in the revised label and provide additional explanation, we wanted to note the following specific points in addition to the addition of puppies to the label:

- Text to comply with Topical Risk Mitigation requirements (as far as we understand) is implemented in the revised label. (Age AND weight limitations, for use ONLY on Dogs/Puppies, Do not use on cats, etc.) We also include reference to the most prominent adverse effect (which is dermal irritation) in the precautionary statements.

- A section on "Use Restrictions" as per the PBO RED DCI has been added, as well as modification of reference to PBO in the Ingredient statement.
- A section of text was added for the text to be included on the individual applicator.
- One efficacy-related claim was added: "Controls fleas ticks and mosquitoes for up to one month". Even though efficacy data does not support a "kills" claim with 90% efficacy for one month, the overall effect in some animals in efficacy tests did support control up to one month, so, in our view, this claim (while less strong) is supported by the existing efficacy data.
- Wellmark believes the safety of this product for cats is documented in the analysis of adverse effect incident data that was included with this submission, and believes that some statement acknowledging that record is appropriate for addition to the label, in order to allow customers to make an informed choice. While the exact nature of that statement may need to be negotiated with the EPA, we are proposing several statements that could reflect the safety record that has been documented:
 - Incidental exposure of cats to this product is not likely to cause harmful effects
 - Can be used in households with dogs and cats
 - Based on testing, accidental exposure to cats from this product is not likely to cause serious harmful effects.

Please let me know if additional information is needed or there are questions about this submission.

Regards,



James McFadden, Ph.D.
Sr. Regulatory Project Manager

1068402

INVOICE NUMBER	INVOICE DATE	SAP DOCUMENT NUMBER	GROSS AMOUNT	DISCOUNT	NET AMOUNT
PRIA FEE-2724-796	04/11/2011	1900138055	3,617.00	0.00	3,617.00
U.S. ENVIRONMENTAL PROTECTION AGENCY			TOTALS --->	3,617.00	0.00
					3,617.00

Commercial/financial information may be entitled to confidential treatment



Wellmark Intl & Farnam Co's, Inc.
Central Life Sciences
1501 E. Woodfield Rd Suite #200W
Schaumburg, IL 60173

Check Number 1068402
Bank of America
Bank of America Illinois
Chicago, Illinois 60697

70-2328

719

PAY *** THREE THOUSAND SIX HUNDRED SEVENTEEN USD***

CHECK DATE
04/14/2011

CHECK AMOUNT
3,617.00

TO THE
ORDER
OF

U.S. ENVIRONMENTAL PROTECTION
AGENCY
WASHINGTON FINANCE CENTER
FIFRA SERVICE FEES
P.O. BOX 979074
ST. LOUIS MO 63197-9000

VOID AFTER 180 DAYS

BY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Wellmark International, 1501 E. Woodfield Rd., Suite 200W	EPA Registration Number/File Symbol 2724-796
Active Ingredient(s) and/or representative test compound(s) S-Methoprene, Etofenprox, PBO	Date June 14, 2011
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Pets and Domestic Animals (Dogs and Puppies)	Product Name RF 2042 (CDSO)

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

June 14, 2011

Typed or Printed Name and Title

James McFadden, Sr. Regulatory Project Manager

RF2042 [CDSO]

Front panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs.) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Front panel – ICON - DO NOT USE ON CATS!

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs & Puppies 10 weeks of age or older]

Effective on indoor and outdoor dogs/puppies

(1 [[3][4][6] monthly treatments) 1 [[3][4][6] Months Supply 24 [[48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks[and [kills and repels mosquitoes for 3 to 4 weeks[

[Protects for up to [Four/4[Weeks[[One month][Four/4 Week [Flea[[Tick[[Mosquito[Treatment[

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes

[Aids in Control of Ticks for up to 30 days[

Contains an Insect Growth Regulator [IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks[up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours[

[Dual Action kills adult fleas and prevents flea development[

[Breaks Flea Life Cycle for [more than 10 weeks[up to [75 days][2.5 months[

[Controls flea reinfestation for [more than 10 weeks[up to [75 days][2.5 months[

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae]]Dual protection (against fleas and ticks))

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle[

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube[

Spreads naturally with dog's/puppy's movement (skin and hair oils)

[Formula][Contains [and] in for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

]Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

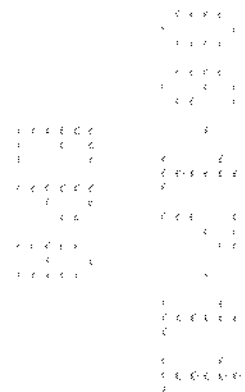
[Fresh][Clean][Scent][Smell[

[Reapply monthly] [Suitable for year-round use][Month[sticker for home calendar

[Satisfaction guaranteed or your money back[

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube[



(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

* (butylcarbityl) (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz/(1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS/PUPPIES LESS THAN 10 WEEKS of AGE

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS!

[Back panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube].
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube] and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

[Alternate Directions for Use for multi-tube application]

- 3 The dog/puppy should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID

If in eyes

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after first 5 minutes, then continue rinsing
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road, 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

TEXT FOR INDIVIDUAL APPLICATOR

Product name

Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ DIRECTIONS BEFORE USING

EPA Reg No.

Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

RF2042 [CDSO]

Front panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs.) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Front panel – ICON - DO NOT USE ON CATS!

[Flea & Tick [& Mosquito] Treatment] [and] Control for Dogs & Puppies 10 weeks of age or older]

Effective on indoor and outdoor dogs/puppies

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week] [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With] S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's/puppy's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

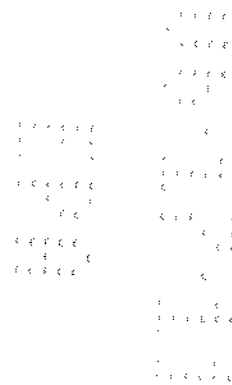
[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]



(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

* (butylcarbityl) (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz/(1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator (tube) (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator (tube) (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS/PUPPIES LESS THAN 10 WEEKS of AGE

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS!

[Back panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube].
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

[Alternate Directions for Use for multi-tube application

- 3 The dog/puppy should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 3 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal: If empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. **If partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID

If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
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Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road, 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

TEXT FOR INDIVIDUAL APPLICATOR

Product name

Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ DIRECTIONS BEFORE USING

EPA Reg No.

Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

RF2042 [CDSO]

Front panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs.) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Front panel – ICON - DO NOT USE ON CATS!

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs & Puppies 10 weeks of age or older]

Effective on indoor and outdoor dogs/puppies

([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks[and]kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's/puppy's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)*..... 5.0%

OTHER INGREDIENTS:..... 61.4%

TOTAL..... 100.0%

* (butylcarbityl) (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS:

One: 0.05 fl oz (1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS/PUPPIES LESS THAN 10 WEEKS of AGE

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS!

[Back panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube].
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots][toy dogs][three spots][small or medium dogs] on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

[Alternate Directions for Use for multi-tube application

- 3 The dog/puppy should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If **empty**: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled**: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID

If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
------------	--

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

TEXT FOR INDIVIDUAL APPLICATOR

Product name

Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ DIRECTIONS BEFORE USING

EPA Reg No.

Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

RF2042 [CDSO]

Front panel - For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs.) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Front panel – ICON - DO NOT USE ON CATS!

[Flea & Tick & Mosquito][Treatment] [and] Control for Dogs & Puppies 10 weeks of age or older]

Effective on indoor and outdoor dogs/puppies

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to]Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Controls fleas, ticks and mosquitoes for up to one month][Monthly treatment for control of fleas, ticks and mosquitoes

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for [more than 10 weeks] up to]75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to]75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's/puppy's movement (skin and hair oils)

]Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs/puppies

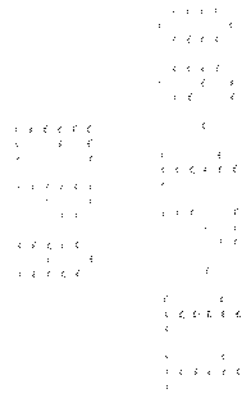
[Fresh][Clean][[Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]



(Front panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)*..... 5.0%

OTHER INGREDIENTS:..... 61.4%

TOTAL..... 100.0%

* [butylcarbityl] (6-propylpiperonyl ether) and related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 0.05 fl oz/(1.5 cc) Applicator [tube] (Toy Dogs)/0.10 fl oz (3.0 cc) Applicator [tube] (Small Dogs)/0.15 fl oz (4.5 cc) Applicator [tube] (Medium Dogs)/0.20 fl oz (6.0 cc) Applicator [tube] (Large Dogs)/0.30 fl oz (9.0 cc) Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS/PUPPIES LESS THAN 10 WEEKS of AGE

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS/PUPPIES. DO NOT USE ON OTHER ANIMALS!

[Back panel]

DO NOT USE ON CATS

Keep cats away from treated dogs for 24 hours. If applied or ingested, contact your veterinarian immediately.

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.][RF2042 [CDSO] treats fleas, ticks, and mosquitoes for up to one month and prevents flea eggs from developing for up to 2.5 months.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS:

The maximum application rate for this product is twice per month, and the second application must be made more than 8 days after the initial application.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's/puppy's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS/PUPPIES

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.
4. Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
- 3 The dog/puppy should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy.

[Alternate Directions for Use for multi-tube application

- 3 The dog/puppy should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog/puppy. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog/puppy. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 5 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on dogs/puppies may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of dogs/puppies with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog/puppy			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If **empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS/PUPPIES LESS THAN 10 WEEKS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Some dogs may experience hair loss or temporary skin irritation at the application site. If signs persist or become more severe, contact veterinarian immediately and report incident to company at 1-800-XXX-XXXX.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

TEXT FOR INDIVIDUAL APPLICATOR

Product name

Etofenprox 30%, S-Methoprene 3.6%, Piperonyl Butoxide 5%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ DIRECTIONS BEFORE USING

EPA Reg No.

Net Contents

[ICON – DO NOT USE ON CATS]

For Use Only on Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs/Puppies 10 Weeks of age or older

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

Wellmark

July 12, 2010

Document Processing Desk (FPL)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Richard Gebken, PM 13

SUBJECT: SUBMISSION OF FINAL PRINTED LABELING FOR RF2042 [CDSO]
EPA REG. NO. 2724-796
PER JANUARY 19, 2010 EPA STAMPED APPROVED LABEL COMMENTS

Dear Mr. Gebken:

Enclosed is a completed EPA Form 8570-1 and 2 copies of final printed labeling incorporating the comment changes noted in the 1/19/10 EPA label approval letter. Additionally, enclosed is one highlighted label with a cover sheet indicating the revisions that were made (red is added text, blue strikethrough is deleted text).

Please call me at 847-330-5376 if you have any questions regarding this submission. Thank you for your assistance on this action.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl

Nancy Huebl
Senior Registration Specialist

enclosure

cc: J. McFadden



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2042 (CDSO)	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated January 19, 2010
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Section - III

1. Material This Product Will be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt. 1.5/3/4.5/6/9 cc	No. per container 1-6		<input checked="" type="checkbox"/> Plastic	
				<input checked="" type="checkbox"/> Glass	
				<input checked="" type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1.5/3/4.5/6/9 cc applicators	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed on cardboard carton			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) 847-330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist	
4. Typed Name Nancy Huebl	5. Date 12-Jul-10	

RF2042 [CDSO]

For Toy (6-12 lbs.), Small (13-31 lbs.), Medium (32-55 lbs.) Large (56-80 lbs) , and Extra Large (81 lbs and over) Dogs

[Flea & Tick [& Mosquito]]Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[(1)]3[4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks]]One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae]]Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Formula][Contains lanolin for coat conditioning]

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS:..... 61.4%

TOTAL 100.0%

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 1.5 cc Applicator [tube] (Toy Dogs)/3.0 cc Applicator [tube] (Small Dogs)/
4.5 cc Applicator [tube] (Medium Dogs)/6.0 cc Applicator [tube] (Large Dogs)/
9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
1-19-10

RF2042 [CDSO]

IMPORTANT! DO NOT USE on DOGS 6 MONTHS of AGE or LESS

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](toy dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

[Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

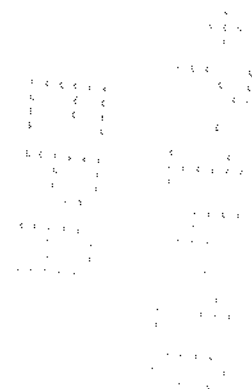
[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID	
If in eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

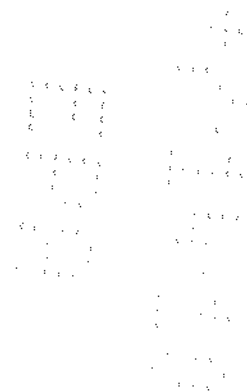
Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road, 200W
Schaumburg, Illinois 60173

[URL]

Made in USA



REGULATORY LABEL DATA SHEET

File Name: Epa fpl 11910.doc **Data Sheet Date:** June 2010
Product: RF2042 [CDSO] **EPA Reg #:** 2724- 796
Approved: FPL submitted 6/11/10 **Supersedes:** 1/19/10

OVERVIEW: FPL submitted to reflect comments from EPA stamped approved label dated 1/19/10

Page #	Description of Major Changes
1	<p>Dog group names revised to match #3 in January 19, 2010 EPA letter, also Extra Large group split into Large/Extra Large per # 3 chart in 1/19/10 EPA letter.</p> <p>Deleted claim "non Irritating" and "Ideal for dogs with sensitive skin" per #1 in 1/19/10 EPA letter</p> <p>Deleted claim, "with special coat conditioning agent, Lanolin" per #4 in 1/19/10 EPA letter</p> <p>Deleted claim, "Based on testing, accidental exposure to cats from treated dogs will not cause serious harmful effects" per #2 in 1/19/10 EPA letter</p> <p>Net contents: revised per #3 chart in 1/19/10 EPA letter</p>
2	<p>Per #3, revised "Intended for use on dogs 6 months of age or older" to DO NOT USE on DOGS 6 MONTHS of AGE or LESS"</p> <p>Directions for Use: revised dog group descriptors based on #3 chart</p>

RF2042 [CDSO]

For Small Toy (6-12 lbs.), Medium Small (13-31 lbs.), Large Medium (32-55 lbs.) and Extra-Large (56-80 lbs) and over, and Extra Large (81 lbs and over) Dogs

[Flea & Tick & Mosquito] [Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to]Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][Formula][with special coat conditioning agent, Lanolin][Contains lanolin for coat conditioning]

Ideal for dogs with sensitive skin

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

~~Based on testing, accidental exposure to cats from treated dogs will not cause serious harmful effects~~

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1)..... 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS:

One: 1.5 cc Applicator [tube] (Small Toy Dogs)/3.0 cc Applicator [tube] (Medium Small Dogs)/
4.5 cc Applicator [tube] (Large Medium Dogs)/6.0 cc Applicator [tube] (Large Dogs)/6
9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! ~~Intended for~~ **DO NOT USE on DOGS 6 MONTHS of AGE or LESS**
READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

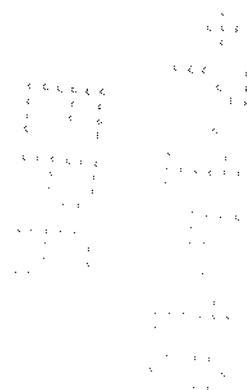
RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [TOY][SMALL][MEDIUM] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](toy small dogs)[three spots](small or medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal



[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

- 1 Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
- 2 Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
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- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____

NOTES: _____

Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If **empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Material to be added to an e-Jacket/Jacket

Reg. No. 2724-796

Description: New Label

1. Placement within the e-Jacket/jacket:

☒ Default: (chronological, top = newest)

☐ File Location: (PDF page number, i.e., "before page 45")

2. ☐ Send to Data Extraction contractors this material:

☒ Newly stamped accepted label

☐ Notification

☐ New CSF

☒ Other: **Correspondence**

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Kevin Sweeney

Phone: 305-5063 Division: RD

Date: 02/04/2010

Created February 4, 2010

FINAL MEETING MINUTES from EPA-Wellmark International Meeting held January 28, 2010

Minutes were drafted by James McFadden and include changes from EPA

Etofenprox Pet Product Issues

1. We discussed pet product planning – listed current Pet product registrations and noted impending product submissions. Differences in AI concentrations between products were noted.

2. Discussion continued based on the issues in the amendment submitted for the ETO CDSO: (Combi Dog Spot-On) (EPA Reg. No. 2724-796)

A. Some Revised Marketing claims were accepted (The statement: "Contains lanolin for coat conditioning." is acceptable)

B. New (confirmatory) efficacy study required.

EPA claimed that most studies currently reviewed employ random attachment. They suggested that we pre-qualify for ticks (instead of for fleas as we sometimes do) and use more ticks to begin with in order to cope with the effects for loss due to grooming.

C. Revised dose groups were accepted in the amendment. Question – will these groups be affected by the blanket mitigation on pet topicals that is coming out soon?

K. Nesci said this discussion should be deferred to until after the announcement is made. Our understanding was that the EPA is not focused on the weight groups so much as the cat-dog interaction issues. The Pet Topical meeting with registrants was delayed because the Assistant Administrator had to be briefed. It is now expected that the announcement will be made sometime in February and that individual meetings with the registrants will be scheduled.

D. In regards to the issue of potential safety to cats, the EPA has indicated an area of possible concern, suggesting an alternative inert be added instead of Lanolin. Maija said that she would be interested in hearing where this concern comes from, since our reviews of the issue did not find it documented in scientific journals.

Deborah McCall responded that the EPA doesn't have hard scientific data, and admitted that it may be anecdotal. But she does claim that some cat varieties (Himalayan, a couple of others) do appear to be attracted to Lanolin. The EPA has concerns about the total number of incidents, EPA seeking ways to protect multi-pet households. Specific label language may be required to separate dogs and cats following treatment.

Wellmark noted that they have not been able to validate this claim in discussions following the meeting with our nutritionists and veterinarians. In fact, lanolin is not an ingredient approved by the Association of Animal Feed Control Officials (AAFCO) for use in pet food. At this point, the association between lanolin acting as an attractant appears to be entirely anecdotal.

J. McFadden asked if there was a difference in sensitivity to incident reports – we are seeing a very low rate of deaths per million does sold.

Deborah McCall responded that it isn't just deaths. Major incidents can result in significant costs to the owners.

K. Nesci commented that EPA is broadly concerned about dog/cat interactions – consumers aren't going to know what the A.I. is and whether there is a serious issue or not, therefore, some mitigation measures will apply to all pet topicals.

3. Discussion of the companion animal safety issues. Maija began with a review of the Max-Tox strategy, intended to support All etofenprox pet products and also mentioned that the statistical analysis prepared by the ASPCA (in the report amendment) had found that the clinical signs were only significant at the 5X dose level.

K. Nesci asked for clarification of the amendment and whether the statistical analysis was included (it was).

Deborah McCall stated that Byron Backus had been tied up with the pet topical issue for three months – she has given no priority to the review. Her priorities are driven by the PRIA issues first and the non-fast track amendments second, then whatever other major issues she has to deal with (like the pet topical issue). Current priorities exceed personnel availability.

Due to the issue of Wellmark submitting the action to the Agency as a rebuttal and not a PRIA amendment no specific time frame for the review is given. Wellmark may consider submitting an amendment under PRIA in order to get a more predictable review time.

4. As a final issue before the meeting broke up, we discussed whether the companion animal safety issues for the Pet Spray and Shampoo could be separated from the topical, considering the much lower application rates. EPA may be willing to consider this issue, and they suggested that we should cite the ASPCA statistical analysis included in the amendment in the data matrix for the low end spray and shampoo products.

Meeting Attendees

Kevin Sweeney, EPA
Kimberly Nesci, EPA
Deborah McCall, EPA
Byron Backus, EPA

James McFadden, Wellmark International
Steven Spaulding, Wellmark International
Maija Mizens, Wellmark International



Etofenprox Pet Product issues

January 2010 EPA Meeting

Current and Planned ETO Pet Products

For summary purposes, the table below shows current and planned etofenprox-based pet products.

2006 2724-504 RF2004 (CCSO)	40.0% ETO, 3.6% S-Mth
2009 2724-796 RF2042 (CDSO) -	30.0% ETO, 5% PBO, 3.6% S-Mth
2009 2724-797 RF2063 PET SPRAY	0.50% ETO, 1.75% PBO, 0.27% S-Mth
2010 2724-XXX RF2112 & RF2059 Shampoo	0.10% ETO, 1.14% PBO, 0.10% S-Mth
2010 2724-XXX RF2127 & RF2126 Pet Spray	0.25% ETO, 0.75% PBO, 0.10% S-Mth

Issues By Product

2724-796, CDSO

- 1. Amendment submitted last August rec'd – issue 3:
Claims for no adverse effects on cats – not allowed
(in fact, EPA has significant concerns)**

But:

ETO/PBO combinations were tested in the CAS studies for the Pet Spray – PBO level tested was 2-8X higher than the dose in 6mL of CDSO

All deaths attributed to the Cat Spot On in 2008 are not attributed to proper use (improper use, symptoms inconsistent with etofenprox, or underlying disease condition (death rate 8 per 1 million doses sold)

Lanolin and cats – lanolin is in numerous pet products – we are unable to find scientific documentation that lanolin is attractive to cats

Issues By Product

2724-796, CDSO AND 2724-797, RF2063 Pet Spray

2. Puppy CAS rejected

TRB's major concerns was:

- Minor adverse effects occurred in the 1X treatment group; the study was not considered to provide an acceptable margin of safety.**
- Wellmark response to DER submitted 8/21; included statistical analysis by S. Hansen et al.**

Where do we stand on this review?

Issues By Product

2724-796, CDSO

1. Amendment submitted last August rec'd – issues 1&2:

- Marketing claims – revised wording accepted**
- Change in dose volume for XL dogs – modified
(there will now be 5 skus, change delayed to 2011)**
- We will schedule new efficacy**

**Q. – Will we face issues as part of topical review?
(Will these groups be affected by the pending
mitigation?)**

EDSO Dose Groups and Volume

Class	Current	Proposed	Accepted
Toy Dogs			6-12 lbs, 1.5mL
Small dogs	5-15 lbs, 1.5mL	6-12 lbs, 1.5mL	13-31 lbs, 3.0mL
Medium dogs	16-30 lbs, 3.0mL	13-31 lbs, 3.0mL	32-55 lbs, 4.5mL
Large dogs	31-80 lbs, 6.0mL	32-55 lbs, 4.5mL	56-80 lbs, 6.0mL
XL Dogs	80-150 lbs, 9.0mL	≥56 lbs, 6.0mL	>81 lbs, 9.0mL



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

JAN 19 2010

Mr. James McFadden
Regulatory Project Manager
Wellmark International
1501 E. Woodfield Road
Suite 200W
Schaumburg, IL 60173

Dear Mr. McFadden:

Subject: Non-Fast Track Label Amendment (R340)
Product Name: RF2042
EPA Registration No. 2724-796
Application dated August 31, 2009

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable provided you:

- 1: Remove: "Non-irritating" and "Ideal for dogs with sensitive skin" because the precautionary statements for "Humans and Domestic Animals" indicate that "Repeated exposure to etofenprox can cause skin irritation."
2. Remove: "Based on testing, accidental exposure to cats from treated dogs will not cause serious harmful effects." Please see the Companion Animal Safety data evaluation review (DER) for more details.

3. The name of the group and the weight class **MUST** appear on the label with the dosing directions. Revise the dosing regime as follows:

DO NOT USE on DOGS 6 MONTHS of AGE or less.

Group	Weight Class	Dose Volume
Toy Dogs	6 to 12 lbs.	1.5 ml
Small Dogs	13 to 31 lbs.	3.0 ml
Medium Dogs	32 to 55 lbs.	4.5 ml
Large Dogs	56 to 80 lbs.	6.0 ml
Extra Large Dogs	81 lbs and over	9.0 ml

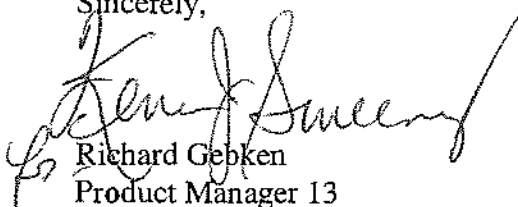
4. Remove "with special coat conditioning agent, Lanolin"

5. The statement: "Contains lanolin for coat conditioning." is acceptable.

6. Since the parasites were placed along the dorsal mid-line following product application in one of the studies, the agency requests confirmatory efficacy data. The study should include application of the product to the dorsal mid-line with parasites distributed on the animal's body in accordance with EPA guidelines. The study results must be submitted by March 1, 2011. Please see the attached DER for more details.

A stamped copy of the label is enclosed for your records. Submit two copies of the revised finished labeling within 30 days of the receipt of this letter. If you have any questions, please contact Kevin Sweeney at (703) 305-5063. Thank you for your cooperation in this matter.

Sincerely,



Richard Gebken
Product Manager 13
Registration Division (7505P)
Insecticide Branch

Enclosure

RF2042 [CDSO]

For Small (6-12 5-15-lbs.), Medium (13-31 16-30-lbs.), Large (32-55 34-80-lbs.) and Extra Large (56 lbs and over 84 -150-lbs.) Dogs

[Flea & Tick & Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] [kills fleas & ticks for 3 weeks] and [kills and repels mosquitoes for 3 to 4 weeks]

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for up to 30 days-weeks]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours][Kills more than 50% of fleas in 2 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls flea reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][New (use for first production only or 6 months)][Formula][with special coat conditioning agent,

Lanolin][Contains lanolin for coat conditioning]

Ideal for dogs with sensitive skin

[Water Resistant] [to keep killing fleas and ticks in humid and wet conditions]

[Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] [Longer applicator tip for easy application to long-haired dogs]

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

Based on testing, accidental exposure to cats from treated dogs will not cause serious harmful effects

Alternate Applicator claims: Unique applicator [tube] with flow control

[no drip][no mess][application][applicator][tube]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One: 1.5 cc Applicator [tube] (Small Dogs)/3.0 cc Applicator [tube] (Medium Dogs)/
4.5 6-9 cc Applicator [tube] (Large Dogs)/69.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 19 2010
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

2724-796

RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [SMALL][MEDIUM] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](small dogs)[three spots](medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

[Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If **empty:** Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If **partially filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173
[URL]
Made in USA

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 9, 2009

MEMORANDUM

Subject: Name of Pesticide Product: RF 2042 (CDSO)
EPA Reg. No. /File Symbol: 2724-796
DP Barcode: DP 369326
Decision No.: 419448
Action Code: R340
PC Codes: 067501 (Piperonyl butoxide: 5%)
105402 (S-methoprene: 3.6%)
128965 (Etofenprox: 30%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Dec. 9 2009

To: Kevin Sweeney/Richard Gebken, RM 13
Insecticide Branch
Registration Division (7505P)

DMcB

Registrant: WELLMARK INTERNATIONAL

FORMULATION FROM LABEL:

Active Ingredient(s):

128965 Etofenprox	30.0%
105402 S-Methoprene	3.6%
067501 Piperonyl butoxide	5.0%

<u>Other Ingredient(s):</u>	61.4%
TOTAL	100.000%

ACTION REQUESTED: The Risk Manager requests:

“Please review labelling of etofenprox product and associated discussion in the attached MRID.”

BACKGROUND:

The material received for review includes a cover letter from the registrant dated August 31, 2009, a regulatory label data sheet from the registrant indicating revisions, and a document (MRID 47844001) titled: "Evaluation of the toxicity of Dog Spot-on RF2042 [CDSO] to Cats and Kittens." The two proposed label revisions which are relevant to toxicity are 1) [Non-Irritating][Formula] [with special coat conditioning agent, Lanolin][Contains lanolin for coat conditioning] Ideal for dogs with sensitive skin, and 2) Based on testing, accidental exposure to cats from treated dogs will not cause serious harmful effects.

COMMENTS AND RECOMMENDATIONS:

1. We can accept a statement indicating that this formulation contains lanolin for coat conditioning. We cannot accept a statement that the formulation is non-irritating or ideal for dogs with sensitive skin.

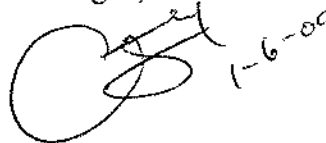
2. Although the material in MRID 47844001 references studies on cats and kittens conducted with etofenprox-containing formulations in which no significant adverse effects were observed, the Agency has received incident reports for both the primary registration (2724-504) and distributor products (2724-504-270 and 2724-504-2596) of a 40% Etofenprox and 3.6% S-methoprene containing formulation. These incidents include a total (for 2008) of 82 deaths (by all exposure routes) in cats or kittens. In addition, the presence of lanolin in 2724-796 creates a potential problem, as some cats (particularly Siamese) may be attracted to lanolin (see <http://www.messybeast.com/pica.htm>), and may go out of their way to lick lanolin-treated items. It is also noted that 2724-504 does not contain piperonyl butoxide, which is present in 2724-796 and which could enhance the toxicity of the etofenprox to the cat. Based on these considerations TRB recommends against any statement indicating that accidental exposure to cats from treated dogs will not cause serious harmful effects.

3. Based on the incident reports for EPA Reg. No. 2724-504 and the attractiveness of lanolin to some cats, TRB strongly recommends that lanolin be removed from 2724-796. Otherwise some cats in multiple-pet households will ingest this product by licking or grooming the dog's treated coat.

Efficacy Review

Date: January 6, 2010

Efficacy Reviewer: Clayton Myers, Ph.D., Entomologist, RD-IB
myers.clayton@epa.gov
703-347-8874



Risk Manager Rev.: Kevin Sweeney

Product: RF 2042 (CDSO)

EPA Reg. #: 2724-796

A.I.'s: Etofenprox (30.0%), S-Methoprene (3.6%), Piperonyl Butoxide (5.0%)

Decision #: 419448

DP #: 369329

Submission: R340, Amendment

MRIDs: Submitted: 47844002

GLP: No

MRID 47844002

Title: RF2042 (CDSO), EPA Reg. No. 2724-796 Summary of Efficacy Data

Guideline: OPPTS 810.3300

Materials and Methods: Various; a summary response to prior efficacy reviews and clarification on new pet dosing proposal

Study Summary of the Results:

1. Adequate flea kill was demonstrated by study 3344 within 15 minutes (i.e., speed of kill claims)
2. Tick control for ADT and BDT exceeded 80% for 30 days
3. Flea control was greater than 90% for 23 days
4. Inhibition of flea development exceeding 98% lasted for 100 days
5. Inhibition of mosquito blood feeding lasted for 28 days for all 3 species of mosquitoes.
6. *Ixodes* tick mortality was greater than 95% for 45 days (*in vitro*).

7. A new dosing scheme is proposed with volume of treatment based on the animal's surface area rather than body weight, for 4 new proposed weight ranges.
8. An argument is presented regarding the placement of parasites from a previous study (along the dorsal midline of the animal rather than anatomically distributed, per the 810.3300 guideline).

Entomologist's Observations/Discussion:

Flea data was reviewed and supports the new proposed speed of kill claim.

While the new dosing scheme (based on a matrix of surface area to weight conversions) is adequate to support the reshuffling of dog weight classes and the addition of a 4.5 mL dosing option, the open-ended top classification still runs the risk of under-treating exceptionally large dogs. While open-ended dosing may be present on other labels, this has been a recurring issue that the Agency seeks to rectify, especially in situations where the top group includes animals as small as 50 lbs. While a 150 lb animal might not require triple the dose of a 50 pound animal (using your proposed dosing scheme as an example, and based on the nature of the surface area to weight relationship you describe), it certainly would require a significantly higher dose than what would be applied to even a median sized animal in what would become a large and highly variable weight class (e.g., certainly dosing for an 80-100 lb dog is not adequate for a 140-150 dog). There must still be adequate dosing classification for dogs weighing greater than 80 pounds on this product label, unless the dosing matrix (comparing weight to surface area) can be extended to show how dosing for animals would calculate out, up to 150 lbs. As currently listed (and presented in the April 1 meeting), the dosing based on surface area for very large dogs was not supported by the presented matrix, and presumably 125-150 lb dogs would receive less than ~1500 g AI/BSA square meter, which is the lowest concentration shown to be efficacious in your studies. Therefore, in that prior meeting, it was decided that dosing could be listed on the label up to the point where the matrix showed that an adequate dose was delivered. It was determined based on the matrix you presented that an 8 mL dose was minimally adequate for dogs weighing up to 125 pounds.

Given the new dosing proposal, and given the desire by the company to have an open ended dosing statement for the largest class of dogs, which would now again include dogs over 125 lbs, a 9 mL dose and dispenser must be included for those dogs 81 lbs and higher (i.e., 'exceptionally large dogs') with appropriate directions for use. A 9 mL dose would ensure adequate a.i. dosing for animals up to a reasonable maximum size encountered in the pet market of 150 lbs. Alternatively, the company would be allowed to revert to the agreement reached at the 1 April meeting, whereby an 8 mL dispenser could be included with a notation on the label indicating that an 8 mL application is adequate to treat dogs between 81 and 125 lbs.

The tick data from Study Number 3268 were reviewed and the data supports the aids in control claim for ticks up to 30 days.

While the registrant argues that placement of ticks along the dorsal midline is common for efficacy studies (to decrease the loss of ticks due to scratching), the 810.3300 guideline is clear in stating that arthropods are to be placed with sufficient anatomical distribution. In addition to

better simulation of natural infestations, this also helps avoid bias in the studies that could occur by placing insects in areas of highest a.i. concentration (especially important for spot-ons, which according to label directions and study protocols, were applied along the dorsal midline). While parasite losses due to scratching are a possible issue, this effect would have been seen in both the treated and control animals and could be addressed by the addition of more parasites. Numerous studies have been submitted to the Agency using the proper anatomical distributions as listed in the guideline without any compromise to the integrity of study statistics or efficacy measurement. This issue is one of the reasons that animals are prequalified for tick and flea infestations, so that study animals can be chosen based upon having high rates of parasite retention. While the flea and tick claims were not and should not be denied outright due to this study shortcoming, the registrant should submit some sort of conditional data demonstrating efficacy to parasites that are properly placed elsewhere on the animal's body. This study would not need to be a full-sized study with animals of all size groups, etc. Instead, the data requirement could be a smaller 2 treatment study (i.e., treatment and control only) on a population of animals in the middle of the company's dosage matrix (i.e., medium sized dogs where the dosage per animal surface area is lowest, e.g. ~1500 g AI/BSA in square meters). Furthermore, such data could be taken from a randomly selected subset of data from another efficacy study being conducted, perhaps for a parallel or future submission.

Overall Review of Efficacy Label Claims and Directions:

1. New dosing as listed on the submitted amended label is acceptable only if an additional classification is made for exceptionally large dogs (81 lbs and up) to be dosed with 9 mL of product. Alternatively, the labeling may revert back to the agreement from the 4-1-09 meeting with the Agency, whereby the old dosing scheme would be used, and an 8 mL treatment would be put in place for dogs between 81 and 125 lbs.
2. The "Aids in control of ticks for up to 30 days" claim is acceptable.
3. "Kills more than 50% of fleas in 2 hours" is acceptable.
4. "[Water resistant][to keep killing fleas and ticks in humid and wet conditions]" is acceptable.

Edit	New Message	Reply\Reply	Reply\Reply with History	Reply\Reply without Attachment(s)	Reply\Reply to All	Reply\Reply to All with History	Reply\Reply to All without Attachment(s)	Forward	Delete	Co Ne To
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**Richard
Gebken/DC/USEPA/US**

10/23/2009 08:06 AM

To: Kevin Sweeney/DC/USEPA/US@EPA
cc
bcc
Subject: Re: Pet product questions

Kevin,

I looked back at the communications dated April 1, 2009.

We can revisit the "Nonirritating" claim, if there is evidence in the incident data that refutes the claim.

The same scenario would also apply to Hartz if they wanted to add the claim.

The 3 month supply claim is just that. I certainly doesn't imply that it protects the pets for 3 months.

Richard

♥Kevin Sweeney---10/23/2009 07:34:31 AM---I will call S. Schatzow today. Note that you may have the meeting minutes from an April 2009 meeting with Wellmark in your email

From: Kevin Sweeney/DC/USEPA/US
To: gebken.richard@epa.gov
Date: 10/23/2009 07:34 AM
Subject: Pet product questions

I will call S. Schatzow today.

Note that you may have the meeting minutes from an April 2009 meeting with Wellmark in your email. They were sent by either Jim McFadden or Steve Spaulding in mid to late April.

I will not be in the office again until Nov 2 and I will search for them at that time. I am not bringing my epa computer with me because it takes all day to boot up from a remote location. I have my personal laptop with me to check mail etc.

Essentially -

the tick data support 21 days and I am pretty sure there are other labels that state supply times that do not apply to all pests. This include etofenprox and also some of the fipronil products because I can't remember fipronil lasting 30 days against mosquitoes so a lesser claim was allowed on the labels that Ann was doing.

Mosquitoes - they got good results against Anopheles and Aede. As Steve Schatzow indicates the Culex were not that good. We had them drop Culex based claims and remove any West Nile virus claims. Instead they were restricted to just 'mosquitoes'.

Non-irritating was discussed and we let them have it. They dropped the cosmetic claims.

I still have to look at flea and tick parts of the study but I thought we resolved the application issue and that the protocol was fine. Clayton did a pretty thorough review.

Kevin

Kevin
Kevin J. Sweeney, Senior Entomologist
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001
+1 703 305 5063

Memorandum

Date: 09 / 04 / 09

To: PM 13, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 3, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-SEP-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Decision Seq: 419234	Action Code: 570, CONDITIONAL REGISTRATION FOLLOW-UP; DATA REQUIRED	Decision Status
FFS Start Date:	Tentative Ind: No	Tracking
Due Date: 12-Dec-2009	75-Day Due Date:	Create Resubmission
OPP Target Due Dt:	FFS Original Decision:	FFS Letters
Negotiated Due Dt:	FFS EUP Decision:	Waiver Documentation
Registrant:	FFS Primary Decision:	Action Code History
Response Due Date:	Start/Stop Clock: FQPA Clock:	
Current Status: PENDING (31-Aug-2009)	Days Elapsed:	

Decision Comments	Payment	Unmatched Payments	75 Day Letters
Meetings & Milestones	FFS Information	FFS Negotiated Due Dates	OPP Target Due Date
Decision Ownership	Receipts	Data Package	Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S 85647D	Sweeney, Kevin	2724-796	12-Dec-2009	PENDING

Response to rejected companion animal safety study

21-Day Screen Completed by
Contractor

21-Day Expires on 9-22-09

Jacket # 2724-796
MRID# 478440

Content Screen: Recommended to
Pass/Fail

86-5 Review: **Passed**/Failed/NA

Transfer This Jacket to:

LINDA ARRINGTON



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 2, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-419448
EPA File Symbol or Registration Number: 2724-796
Product Name: RF 2042 (CDSO)
EPA Receipt Date: 01-Sep-2009
EPA Company Number: 2724
Company Name: WELLMARK INTERNATIONAL

STEVE SPAULDING
WELLMARK INTERNATIONAL
1501 E. WOODFIELD ROAD, SUITE 200 WEST
SCHAUMBURG, IL 60173

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script, reading "Teresa Downs", is written over a horizontal line.

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

^W
{857078N~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☒ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 13

Receipt No.

S- 857078

EPA File Symbol/Reg. No.

2724-796

Pin-Punch Date:

9/1/2009

~~NO~~ This item is NOT subject to FFS action.

Action Code:

Requested: 2340

Granted: 2340

Amount Due: \$ 3444.00

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: W. Rasmussen

Date: 9/2/09

Remarks:

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-1-09

Experts In-Processing Signature: M F HARRINGTON

Date 9-2-09

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>2724-796</u>		EPA Receipt Date: <u>9-1-09</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)			yes	no	X
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack) a) Selective Method (Fee category experts use) b) Cite-All (Fee category experts use) c) Applicant owns all data (Fee category experts use)			yes	no	X
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- studies passed 86-5 Review

- 09/08

Data Matrix and Certification w/ Respect to citation of Data sent in order to complete package

- JB -

MRIP 478440

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [[link to http://www.epa.gov/oppr001/inerts/lists.html](http://www.epa.gov/oppr001/inerts/lists.html)] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [[Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [[link to http://www.epa.gov/oppr001/inerts/tips.pdf](http://www.epa.gov/oppr001/inerts/tips.pdf)] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRLA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

ipt for Rejection Phone call

Contact Name: Jamay McFadden
Phone #: 847-330-5369
Email: jmcadden@central.com

First Call/Initials:

Date: 09/08

Time: 10:56

Second Call/Initials:

Date:

Time:

This is JB, EPA contractor.

I'm calling regarding your submission in support of
2724-796 RF 2042 (CDSO).

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

↳ data matrix

↳ certification w/respect to citation of data (efficacy & toxicity data)

jmcadden@central.com

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



EPA Submission: 2724-796, RF 2042 (CDSO)

Jennifer Brandon to jmcadden

09/08/2009 11:02 AM

Cc: Sree Nair

Hi Mr. McFadden,

This is a follow-up email with regard to your submission in support of the registration of the product **RF 2042 (CDSO) (EPA Registration Number: 2724-796)**. We have found the following deficiencies regarding this submission

- **The Certification with Respect to Citation of Data (EPA Form 8570-34) and the Data Matrix Form (EPA Form: 8570-35)** are missing from the application package.

You can find these forms in the following website: <http://epa.gov/pesticides/registrationkit/>

You can send these forms and the corrected pages either by fax to 703-305-5060/ ATTN: Jennifer Brandon or email them to brandon.jennifer@epa.gov. If you have any further questions, please feel free to call me.

Thanks,

Jennifer Brandon
Data Analyst (EPA Contractor)
2777 S. Crystal Drive
Arlington, VA 22202
Ph: 703-305-0074
Fax: 703-305-5060
Email: brandon.jennifer@epa.gov



RE: EPA Submission: 2724-796, RF 2042 (CDSO)
James McFadden to: Jennifer Brandon

09/08/2009 11:53 AM

Hi, Jennifer -

Thanks for your e-mail. I have attached the signed and scanned forms that you requested.

Thank you for your assistance in this matter.

Regards,

James McFadden
Regulatory Project Manager
Wellmark International
Central Life Sciences

Tel: 847-330-5369

-----Original Message-----

From: Brandon.Jennifer@epamail.epa.gov [
mailto:Brandon.Jennifer@epamail.epa.gov]
Sent: Tuesday, September 08, 2009 10:02 AM
To: James McFadden
Cc: Nair.Sree@epamail.epa.gov
Subject: EPA Submission: 2724-796, RF 2042 (CDSO)

Hi Mr. McFadden,

This is a follow-up email with regard to your submission in support of the registration of the product RF 2042 [CDSO] (EPA Registration Number: 2724-796). We have found the following deficiencies regarding this submission.

- The Certification with Respect to Citation of Data (EPA Form 8570-34) and the Data Matrix Form (EPA Form: 8570-35) are missing from the application package.

You can find these forms in the following website:
<http://epa.gov/pesticides/registrationkit/>

You can send these forms and the corrected pages either by fax to 703-305-5060/ ATTN: Jennifer Brandon or email them to brandon.jennifer@epa.gov. If you have any further questions, please feel free to call me.

Thanks,

Jennifer Brandon
Data Analyst (EPA Contractor)
2777 S. Crystal Drive
Arlington, VA 22202
Ph: 703-305-0074
Fax: 703-305-5060
Email: brandon.jennifer@epa.gov

Disclaimer: This communication and any attachments contain private, confidential, privileged and/or proprietary information intended solely for the Recipient(s) named above. If you are not the intended Recipient, any use, dissemination, distribution or copying of the communication is strictly prohibited. If received in error, we apologize and ask that you please notify

Completion of 21-Day Content Screen

PM- 13

EPA Reg. # (File Symbol) 2724-796

Decision # **D** 465 448

Data package delivered to
you on 9/10/05.
(date)

Jacket/Mini-jacket will be
transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21-Day Content Team

Receipt for Section 3

S: 857078

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 2724 WELLMARK INTERNATIONAL V

Risk Manager: Registration Division, Risk Management Team 13

Product #: 2724-796 Product Name: RF 2042 (CDSO)

Override:

Me Too Section3: Me Too Product Name:

Application Date: 31-Aug-2009

OPP Rec'd Date: 01-Sep-2009

Front End Date: 01-Sep-2009

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Amendment to address marketing claim

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Study	
Paper Label	
<	>

View/Edit

New Ingredient
Request Date:
New Ingredient
Received Date:

1039879

INVOICE NUMBER	INVOICE DATE	SAP DOCUMENT NUMBER	GROSS AMOUNT	DISCOUNT	NET AMOUNT
PRIAFEE RF2042	08/24/2009	1900078872	3,444.00	0.00	3,444.00
U.S. ENVIRONMENTAL/PROTECTION AGENCY			TOTALS ---->	3,444.00	0.00
					3,444.00

Commercial/financial information may be entitled to confidential treatment

THIS CHECK IS PRINTED ON CHEMICAL REACTIVE PAPER WHICH CONTAINS A WATERMARK - HOLD UP TO A LIGHT TO VIEW

CENTRAL Life Sciences

Wellmark Intl & Farnam Co's, Inc.
Central Life Sciences
1501 E. Woodfield Rd Suite #200W
Schaumburg, IL 60173

Check Number 1039879

70-2328

719

Bank of America
Bank of America Illinois
Chicago, Illinois 60697

PAY *** THREE THOUSAND FOUR HUNDRED FORTY-FOUR USD***

CHECK DATE
08/31/2009CHECK AMOUNT
3,444.00

VOID AFTER 180 DAYS

TO THE ORDER OF
U.S. ENVIRONMENTAL PROTECTION
AGENCY
WASHINGTON FINANCE CENTER
FIFRA SERVICE FEES
P.O. BOX 979074
ST. LOUIS MO 63197-9000

BY

Robert D. Roden

1039879



United States
Environmental Protection Agency
Washington, DC 20460

☐
☒
☐

Registration
Amendment
Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2402 (CDSO)	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1501 East Woodfield Road, Suite 200 West Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Label amendment to address marketing claims as discussed in an April 1 phone conference with EPA. The amendment addresses 3 issues: 1. Addition of claims related to the low potential for adverse effects on cats; 2. Submission of a request to change the dose volume and retail container sizes; 3. Marketing claims related to coat conditioning properties of the shampoo. Since this amendment is supported by data that can be reviewed in RD, it should be assigned to PRIA category R340. For questions, contact: James McFadden; tel: (847) 330-5369; fax: (847) 330-5391; E-mail: jmcadden@central.com

Section - III

1. Material This Product Will be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted	It "Yes" Unit Packaging wgt. 1.5/3/4.5/6 cc	No. per container 3	It "Yes" Unit Packaging wgt. _____ No. per container _____
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.5/3/4.5/6 cc applicators	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product	
		<input checked="" type="checkbox"/> Other printed on cardboard carton	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name James McFadden	Title Regulatory Project Manager	Telephone No. (Include Area Code) (847) 330-5369
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Project Manager	
4. Typed Name James McFadden	5. Date Aug. 31, 2009	

Wellmark™

James McFadden, Ph.D.
Regulatory Project Manager

Wellmark International
1501 E. Woodfield Rd
Suite 200W
Schaumburg, IL 60173

847-330-5369 phone
847-330-5391 fax

jmcfadden@central.com
www.centrallifesciences.com

August 31, 2009

Richard Gebken, PM 13
Registration Division
Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

**Subject: Submission of a Label Amendment for a Product Containing Etofenprox:
EPA Reg. No. 2724-796, RF2042 (CDSO)**

Dear Mr. Gebken:

Enclosed with this letter please find an application for a Label Amendment for the above-named product. This label amendment addresses a number of wording issues related to marketing claims that could not be addressed prior to registration. These issues were discussed by phone conference with EPA on April 1, 2009, and the issues are the same as discussed in that conference.

Because this label amendment is supported by data that can be reviewed in RD, we expect that it will be assigned to PRIA category R340, with a PRIA fee of \$3444. A check for that amount has been submitted to the appropriate lockbox and a copy is enclosed.

There are three main issues addressed in the amendment as follows:

1. Claims related to the potential for adverse effects on cats

The Notice of Registration dated March 10th, In 3.j, it was noted: "Remove: "Based on testing, accidental exposure to cats will not cause serious harmful effects." and "Can be used in households with dogs and cats." Please see the Companion Animal Safety Study recommendations."

The recommendations state: It is also noted that the label claims: "Can be used in households with dogs and cats" and "Based on testing, accidental exposure to cats will not cause serious harmful effects" [presumably based on additional studies which have been submitted to the Agency] have not yet been evaluated and accepted.

These claims, as noted in the cover letter submitted with the application, are supported by Wellmark's etofenprox cat spot-on, which contains 40% etofenprox:

"Wellmark has an etofenprox-based cat spot on (EPA Reg. No. 2724-504) that contains 40% etofenprox. Wellmark has conducted and submitted a Companion Animal Safety study (in cats) to support this product (MRID 46513409). The results of this study found that:

No treatment-related findings were noted in food consumption, body weight and clinical pathology indices. The test material, RF2004[CCSO], produced no systemic effects when applied dermally to the dorsal neck area of young adult cats. Minimal dermal effects of unknown cause were noted in three cats at the highest doses.

Although the product was applied dermally, due to cats self-grooming activity, some oral exposure would be expected and was therefore tested in that study. Since direct application of a formulation containing 40% etofenprox to cats does not cause severe adverse reactions, (and the safety study for the cat spot on showed a significant margin of safety) it can be inferred that accidental direct application or indirect exposure of cats to etofenprox from a dog spot-on treatment should not cause severe adverse effects."

In response to this issue, Wellmark is submitting a report that specifically reviews the potential toxicity of the RF2042 (CDSO) to cats (Mizens, 2009).

2. A second issue is the recommendation to change dose volume for extra large dogs:

In 3.k., it was noted: Change the highest dose (Extra Large Dogs) from 8.0 cc to 9.0 cc to be consistent with dose titration in your studies. There is no evidence that a lower dose will be efficacious.

This was not explained in our application, but although the dose titration established the effective dose, it is well understood that efficacy is based on the mg/m² on the fur, and body surface area does not increase proportionately to body weight. Thus extra large dogs have proportionately less surface area than smaller dogs. This also means it is possible to translate the efficacy data that was initially developed on a mg/kg basis to cover efficacy based on mg/m².

And in fact, that is what was done. The tables in the enclosed report show that the medium dogs (dogs actually used in the efficacy studies) have a lowest coverage of ~1.6 g/m². But the largest groups also can cover the animals with an essentially equivalent mg/m² dose of etofenprox.

As discussed in our April 1, 2009 phone conference, it was agreed that the EPA would accept an alternate proposal keep the volume for the largest group at 8 mL, but reduce the top weight limit for the extra large dogs. If we reduce the range of the Extra-large Dog size to 81 to 125 lbs, the lowest coverage and average for the top group fall closer to the lowest levels for the medium dogs.

However, since that time, our Marketing group has determined that they would like all the dose groups revised, and the highest weights are no longer supported. The current proposal (table below) is essentially equivalent to weight divisions for competitor products.

Group	Weight Range	Dose Volume
Small Dogs	6 to 12 lbs	1.5 mL
Medium Dogs	13 to 31 lbs.	3.0 mL
Large Dogs	32 to 55 lbs.	4.5 mL
Extra-Large Dogs	56 lbs and over	6.0 mL

A summary of the efficacy studies submitted previously and calculation of the dose on a mg/m² basis is provided for review (Rudolph, 2008). Note also that competitor products also have open-ended size groups for extra-large dogs, so we expect the same allowance.

3. The third general issue is marketing claims that were removed in label review:

a. Coat Conditioning: In f), it was noted: Non-Irritating/Coat Conditioning Formula-Non-irritating is acceptable, but a coat conditioning claim might not be allowed: implied use of a pesticide for some purpose other than killing pests, 40 CFR 156.10

It is true that statements about the value of a pesticide for purposes other than as a pesticide are prohibited, but it is also true that these claims are commonly allowed on pet products. We have no reason to expect that our product should be treated differently than other pet products. In addition, what is prohibited by the CFR is false or misleading claims about the value of a product – non-pesticidal claims by themselves (that are true) are permitted and are even explicitly permitted in PR 98-10. Since this product does contain lanolin, the coat conditioning claim is based on that ingredient.

Some alternate wording of this claim has been added, such as

"Contains lanolin for coat conditioning"

b. Tick control: The review noted that:

Aids in control of ticks for up to 30 days [one month]-Not acceptable. Should be revised to 3 weeks.

Table 2 from Wellmark International Study Number 3268 is reproduced as an Appendix to this letter. The data in Wellmark International Study Number 3268 report that an average (for Brown dog ticks and American dog ticks) of 57.7% reduction in ticks was achieved on day 30. According to OPPTS Guideline # 810.3300:

"A minimum of 50% reduction must be apparent for an 'aids in control' claim."

Since this study shows that RF2042 meets the criteria, the claim should be allowed.

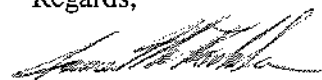
As an additional note in regards to the efficacy testing, it was noted that:

The parasite placement was along the dorsal midline of the animal, which is the same area where treatment was applied. This doesn't meet the standard of 'sufficient anatomical distribution' per 810.3300..... Please explain and justify why application of ticks and fleas were made to the mid-dorsal line where the treatment was made and why it is more appropriate for product evaluation than a random placement of parasites on different areas of the animal.

It is well known that placement of ticks away from the dorsal area results in increased loss of ticks due to scratching. The removal of ticks by dogs (when they are placed in accessible areas) causes degradation of study statistics, and can result in invalidation of studies. The study was conducted with the most practical method for testing efficacy.

Please let me know if you have any questions in regards to this submission or need additional information.

Regards,



James McFadden, Ph.D.
Regulatory Project Manager

Table 2 from Wellmark International Study Number 3268

TABLE 2: AMERICAN DOG TICK AND BROWN DOG TICK EFFICACY DATA

Group 1 Untreated Controls												
Animal ID	Day 1		Day 2		Day 3		16		Day 23		Day 30	
	ADT	BDT	ADT	BDT	ADT	BDT	ADT	BDT	ADT	BDT	ADT	BDT
800946	16	4	24	13	33	24	27	21	44	27	35	37
11	17	22	7	23	17	46	25	27	38	26	32	44
25	19	14	25	11	36	27	15	14	42	21	36	20
7	18	6	6	12	22	26	12	29	32	19	26	34
40905	12	14	17	17	32	18	7	3	27	16	18	11
40913	17	26	11	18	30	23	4	26	32	21	18	14
Total	99	88	90	94	170	164	90	120	215	130	165	160
Geo Mean	16.3	12.0	13.1	15.2	27.5	26.2	12.5	16.6	35.3	21.3	26.5	23.7
Group 2 Treated RF-2042B (Not Wetted)												
5802	12	25	4	2	1	1	2	4	6	0	7	12
6482	23	4	16	5	6	9	0	1	1	1	26	10
3316	5	7	0	0	0	2	1	2	6	1	7	9
100	7	4	0	0	3	4	6	2	5	1	28	12
40824	13	8	1	1	0	2	2	4	11	2	13	18
101	9	4	6	2	4	7	1	0	4	2	7	6
7592	3	7	1	4	0	8	2	3	2	1	3	15
2771	13	4	11	6	8	7	2	0	1	1	16	5
6120	7	14	0	4	4	10	1	4	1	2	3	12
6673	7	4	8	3	14	6	5	1	6	1	7	2
Total	99	81	47	27	40	56	22	21	43	12	115	101
Geo Mean	9.65	7.25	2.99	2.15	2.31	4.91	1.93	1.81	3.92	1.19	10.64	10.52
% Reduction	40.96	39.69	77.17	85.86	91.59	81.26	84.57	89.13	88.90	94.43	59.80	55.60
Group 3 Treated RF-2042B (Wetted)												
2973	6	2	2	0	0	0	3	0	0	0	6	4
9198	11	19	2	1	0	0	0	6	0	3	7	13
99	11	0	5	2	3	4	3	0	4	3	3	2
Total	28	21	9	3	3	4	6	5	4	6	16	19
Geo Mean	9.0	2.9	2.8	0.8	0.6	0.7	1.5	0.9	0.7	1.5	5.1	4.9
% Reduction	44.8	75.8	78.8	94.8	97.9	97.3	87.8	94.5	98.0	92.9	80.8	79.1

TRANSMITTAL DOCUMENT, PAGE 1

1. NAME AND ADDRESS OF SUBMITTER

Wellmark International
1501 E. Woodfield Road
Suite 200 West
Schaumburg, IL 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Submission of Files to Support Label Amendment for RF2042 (CDSO),
EPA Reg. No. 2724-796

3. TRANSMITTAL DATE

August 31, 2009

4. LIST OF DOCUMENTS SUBMITTED

- 47844001 1. Mizens, M. (2009) Evaluation of the toxicity of Dog Spot-on RF2042 (CDSO) to Cats and Kittens, unpublished, Wellmark International Study Number 3617, 13 pp.
- 47844002 2. Rudolph, R. (2009) RF2042 (CDSO), EPA Reg. No. 2724-796: Summary of Efficacy Data, unpublished, Wellmark International Study Number 3643, 9 pp.

5. COMPANY NAME

Wellmark International

6. COMPANY AGENT

James McFadden
Regulatory Project Manager
Wellmark International
1501 E. Woodfield Rd., Suite 200 West
Schaumburg, IL 60173

7. AGENT SIGNATURE  DATE: August 31, 2009

8. COMPANY CONTACT: James J. McFadden PHONE: 847-330-5369

TRANSMITTAL DOCUMENT, PAGE 1

1. NAME AND ADDRESS OF SUBMITTER

Wellmark International
1501 E. Woodfield Road
Suite 200 West
Schaumburg, IL 60173

2. REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Submission of Files to Support Label Amendment for RF2042 (CDSO),
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5. COMPANY NAME

Wellmark International

6. COMPANY AGENT

James McFadden
Regulatory Project Manager
Wellmark International
1501 E. Woodfield Rd., Suite 200 West
Schaumburg, IL 60173

7. AGENT SIGNATURE



DATE: August 31, 2009

8. COMPANY CONTACT: James J. McFadden PHONE: 847-330-5369

REGULATORY LABEL DATA SHEET

File Name: epa amend doses 809.doc **Data Sheet Date:** August, 2009
Product: RF2042 [CDSO] **EPA Reg #:** 2724- 796
Approved: Amendment submitted 8/09 **Supersedes:** 7/24/09

OVERVIEW: Amendment to change dose ranges and add marketing claims

Page #	Description of Major Changes
1	Revise dose sizes (marketing decision), additionally net contents revision Marketing claims: Aids in control of ticks timeframe revised from 3 wks to "up to 30 days" Added flea speed of kill claim Added "Flea" to reinfestation claim (clarity) Deleted "New" reference (over 6 months marketing) Added lanolin conditioning claims, added sensitive skin claim Added humid/wet conditions claim to "water resistant" Added cat exposure claim (to treated dogs) Added new applicator style claims



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Wellmark International, 1501 E. Woodfield Rd., Suite 200W, Schaumburg, IL 60193 (847) 330-5366	EPA Registration Number/File Symbol 2724-796
Active Ingredient(s) and/or representative test compound(s) Ethofenprox, Piperonyl Butoxide, (S)-Methoprene	Date August 31, 2009
General Use Pallet(s) (list all those claimed for this product using 40 CFR Part 158) Pets and domestic animals (dogs)	Product Name RF2042 (CDSO)

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

8/31/09

Typed or Printed Name and Title

James McFadden, Regulatory Project Mgr.

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2622T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: August 31, 2009

EPA Reg No./File Symbol	2724-796
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Page 1 of 1

Applicant's/Registrant's Name & Address	Wellmark International 1501 E. Woodfield Rd., Suite 200 West Schaumburg, IL 60173
---	---

Product	RF2042 (CDSO)
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Ingredients: (S)-Methoprene, Ethofenprox, PBO

[illegible]

MATERIAL TO BE ADDED TO JACKET

REG #

2724-796

11/A11/3

Description:

PR Notice 98-10 changes

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input type="checkbox"/>	new CSF
<input checked="" type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer's

Name:

Terri Stowe

Date:

Phone:

703-305-6117

Division:

RA



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
HUMAN SUBSTANCES

Nance Huebl
Senior Registration Specialist
Wellmark International
1501 East Woodfield Road, Suite 200W
Schaumburg, IL 60173

JUL 30 2009

SUBJECT: Application for Pesticide Notification – Clarify Animal Weight Ranges per South Dakota
RF2042 [CDSO]
EPA Reg. No. 2724-796
Application Dated May 27, 2009

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of this PRN. The label submitted with the application has been date-stamped "Notification" and will be placed in our records.

If you have any questions, please contact me directly at (703) 305-6249 or Terri Stowe of my staff at (703) 305-6117.

Sincerely,

A handwritten signature in black ink, appearing to be "Linda Arrington".

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken/K. Sweeney	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2042 [CDSO]	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International t501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>NOTIFICATION</u> Product Name <u>JUL 3 0 2009</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Per request of S. Dakota, clarify animal weight ranges to avoid overlap of same size in two different groups (5-t5 and 15-30) per PRN 98-10, §N.2&3. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____			
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1.5/3/6/9 cc	No. per container 3	If "Yes" Unit Packaging wgt.		No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1.5/3/6/9 cc applicators		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product			
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other printed cardboard carton			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) 847-330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist	
4. Typed Name Nancy Huebl	5. Date 27-May-09	

Wellmark International
1501 East Woodlawn Road, Suite 200 West
Schoumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

Wellmark

May 27, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Richard Gebken, PM 13

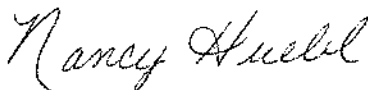
SUBJECT: LABEL NOTIFICATION FOR RF2042 [CDSO]
EPA REG. NO. 2724-796
PER SOUTH DAKOTA REQUEST/CLARIFY SIZE RANGES

Dear Mr. Gebken:

Per PRN 98-10, §II.N. 2 & 3, enclosed is completed EPA Form 8570-1 and 2 copies of highlighted revised labeling for the above product (red is new text, blue strikethrough is deleted text). This change was requested by the State of South Dakota to clarify the weight ranges to avoid overlap (5-15 lb, 15-30 lb, etc.). Therefore, the minimum weight in the three large sizes has been increased by one lb to avoid overlap (16-30 lb, 31-80 lb, 81 to 150 lb). This requires only a change to the size claim, there were no other changes made to the label.

This label change is submitted as a notification because it meets the requirements of PRN 98-10, §II.N. 2 & 3 and: (2) are consistent with 40 CFR Part 156; and (3) involve no change in the ingredients statement, signal word, use classification, precautionary statements, statements of practical treatment (First Aid), physical/chemical/biological properties, storage and disposal, or directions for use. I have enclosed a self-addressed postcard for notification confirmation. If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL



Nancy Huebl
Senior Registration Specialist
nhuebl@central.com

enclosure

cc: J. McFadden/C. Elmi/H. Friedli

TABLE
OF
CONTENTS
PAGE
1
2
3
4
5
6
7
8
9
10
11
12
13
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16
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JUL 30 2009

RF2042 [CDSO]

For Small (5-15 lbs.), Medium (16.5-30 lbs.), Large (31-80 lbs.) and Extra Large (81 to 150 lbs.)

Dogs/Puppies**[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs and Puppies 10 weeks old and older]**

Effective on indoor and outdoor dogs

([1][3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] kills fleas & ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for 3 weeks]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][Formula]

[Water Resistant][Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%**TOTAL** **100.0%**

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

KEEP OUT OF REACH OF CHILDREN**CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One 1.5 cc Applicator [tube] (Small Dogs)/
 One 3.0 cc Applicator [tube] (Medium Dogs)
 One 6.0 cc Applicator [tube] (Large Dogs)
 One 9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs & Puppies 10 Weeks of Age or Older

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS OR PUPPIES. DO NOT USE ON OTHER ANIMALS!

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.

RF2042 [CDSO] works by application directly to the dog's/puppy's skin, not to the hair. When applying, manually push aside dog's/puppy's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [SMALL][MEDIUM] SIZE DOGS AND PUPPIES

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](small dogs)[three spots](medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS AND PUPPIES

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

[Alternate Directions for Use for multi-tube application]

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's/puppy's skin and hair oils will naturally distribute the application over the entire dog/puppy, brushing the dog/puppy 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** *If empty:* Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. *If partially filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON PUPPIES LESS THAN 10 WEEKS OF AGE. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using **ANY** pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
1501 E. Woodfield Road. 200W
Schaumburg, Illinois 60173

[URL]

Made in USA

REGULATORY LABEL DATA SHEET

File Name: RF2042 CDSO epa amend sizes sd 509.doc **Data Sheet Date:** May, 2009
Product: RF2042 [CDSO] **EPA Reg #:** 2724- 796
Approved: submitted 5/26/09 **Supersedes:** 4/23/09

OVERVIEW: submitted per South Dakota request adjusting dog size designations to revise overlap issue

Page #	Description of Major Changes
1	Marketing claims: adjusted three larger sizes by one to avoid overlap in weight ranges

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Page #	Description of Major Changes
1	Marketing claims: adjusted three larger sizes by one to avoid overlap in weight ranges

RF2042 [CDSO]

For Small [5-15 lbs.], Medium [16-30 lbs.], Large [31-80 lbs.] and Extra Large [81 to 150 lbs.]

Dogs/Puppies

[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs and Puppies 10 weeks old and older]

Effective on indoor and outdoor dogs

[(1)[3][4][6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube [applicator] kills fleas & ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks

[Protects for up to] Four[4] Weeks][One month][Four[4] Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for 3 weeks]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to [75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

[Kills 85% of ticks within 48 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][Formula]

[Water Resistant][Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 30.0%

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TOTAL 100.0%

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

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CAUTION

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EPA Reg. No. 2724-796

EPA Est. No. 100-100000000

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In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
 1501 E. Woodfield Road, 200W
 Schaumburg, Illinois 60173
 [URL]
 Made in USA

NOTIFICATION

JUL 30 2009

MATERIAL TO BE ADDED TO JACKET

REG #

2724-796

Description:

PRN 98-10 changes on

PRN 2007-4 changes

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input type="checkbox"/>	new CSF
<input checked="" type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer's

Name:

Owen Becker

Date:

Phone:

3088899

Division:

RD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Nancy Huebl
Product Registration
Wellmark International
1501 Woodfield Road, Suite 200W
Schaumburg, IL 60173

JUL 24 2009

SUBJECT: Application for Pesticide Notification (PRN 98-10)
Request General Label Change (Marketing Claims)
EPA Reg. No. 2724-796
Application Dated July 1, 2009

Dear Ms. Huebl:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 07/01/09 for the above product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action(s) requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, please call me directly at 703-305-6249 or Owen F. Beeder of my staff at 703-308-8899.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Arrington", is positioned above the typed name.

Linda Arrington
Notifications & Minor Formulations Team Leader
Registration Division (7505P)
Office of Pesticide Programs



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Wellmark International/2724-796	2. EPA Product Manager R. Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wellmark International/RF2042 [CDSO]	PM # 13	
5. Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International t501 East Woodfield Road, Suite 200W Schaumburg, Illinois 60173 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name <u>NOTIFICATION</u> JUL 24 2009	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and section II.)

Label notification to add marketing claim "New Formula" and move marketing text from DFU to precede DFU

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input checked="" type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
If "Yes" Unit Packaging wgt. 1.5/3/6/9 cc		No. per container 3	
If "Yes" Unit Packaging wgt. _____		No. per container _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1.5/3/6/9 cc applicators	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label Accompanying Product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other printed on cardboard carton	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Nancy Huebl	Title Senior Registration Specialist	Telephone No. (Include Area Code) (847) 330-5376
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Nancy Huebl</i>	3. Title Senior Registration Specialist	
4. Typed Name Nancy Huebl	5. Date 01-Jul-09	

Wellmark International
1501 East Woodfield Road, Suite 200 West
Schaumburg, Illinois 60173
847 330 5300
www.wellmarkinternational.com

Wellmark

July 1, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs 7504P
U.S. Environmental Protection Agency
Room S-4900 One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Richard Gebken, PM 13

SUBJECT: LABEL NOTIFICATION FOR RF2042 [CDSO]
TO ADD MARKETING CLAIM/EPA REG. NO. 2724-796

Dear Mr. Gebken:

Per PRN 98-10, §II.K.5, enclosed is completed EPA Form 8570-1 and 2 copies of highlighted revised labeling for the above product (red is new text, blue strikethrough is deleted text). We are adding "New" as a marketing claim since this is the first etofenprox/S-methoprene dog topical and it was not included in the initial submission. The term will only be used on initial production or production within a six month timeframe. Additionally, we are moving a marketing general information paragraph out of the Directions for Use to precede the DFU and notating as optional text if spacing issues arise on the packaging.

This label change is submitted as a notification because it meets the requirements of PRN 98-10, §II.K.5. I have enclosed a self-addressed postcard for notification confirmation. If you have any questions please, call me directly at 847-330-5376. Thank you for your assistance in this matter.

Yours sincerely,
WELLMARK INTERNATIONAL

Nancy Huebl

Nancy Huebl
Senior Registration Specialist
nhuebl@central.com

enclosure

cc: J. McFadden/C. Elmi/C. Purcell

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JUL 24 2009

RF2042 [CDSO]

For Small (5-15 lbs.), Medium (16-30 lbs.), Large (31-80 lbs.) and Extra Large (81 - 150 lbs.) Dogs
[Flea & Tick & Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[[1][3][4][6] monthly treatments) [1][3][4][6] Months Supply]24][48] doses

Each tube [applicator] kills fleas & ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea][Tick][Mosquito] Treatment]

[Aids in Control of Ticks for 3 weeks]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

(more than 10 weeks[up to [75 days][2.5 months])

(Starts Killing Fleas and Ticks within 15 minutes)

(Kills 85% of ticks within 48 hours)

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

]With]S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube]

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][New (use for first production only or 6 months)]Formula]

[Water Resistant][Fast Acting][Long Lasting][Kills Fleas and Ticks by Contact]

[Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

(Satisfaction guaranteed or your money back)

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL **100.0%**

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and 1.00% related compounds

KEEP OUT OF REACH OF CHILDREN**CAUTION**

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS: One 1.5 cc Applicator [tube] (Small Dogs)/
 One 3.0 cc Applicator [tube] (Medium Dogs)
 One 6.0 cc Applicator [tube] (Large Dogs)
 One 9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!

[RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

~~RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.~~

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [SMALL][MEDIUM] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](small dogs)[three spots](medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

[Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
 1501 E. Woodfield Road. 200W
 Schaumburg, Illinois 60173

[URL]

Made in USA

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REGULATORY LABEL DATA SHEET

File Name: epa notif new 709.doc **Data Sheet Date:** July, 2009
Product: RF2042 [CDSO] **EPA Reg #:** 2724- 796
Approved: submitted 7/1/09 **Supercedes:** 6/29/09

OVERVIEW: Per PRN 98-10, §II.K.5. Added marketing claim for "New Formula" (first etofenprox/S-Methoprene formula for dog topical), will be used for first production only or 6 months,

Page #	Description of Major Changes
t	Marketing Claims: Added marketing claim for "New Formula" (first etofenprox/S-Methoprene formula for dog topical), will be used for first production only or 6 months,
2	Introductory Marketing paragraph (general Marketing information) moved from Directions for Use to precede DFU and marked as optional general marketing information (was inadvertently included in DFU at initial submission)

REGULATORY LABEL DATA SHEET

File Name: epa notif new 709.doc Data Sheet Date: July, 2009
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Approved: submitted 7/1/09 Supercedes: 6/29/09

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RF2042 [CDSO]

For Small (5-15 lbs.), Medium (16-30 lbs.), Large (31-80 lbs.) and Extra Large (81 - 150 lbs.) Dogs
[Flea & Tick [& Mosquito][Treatment] [and] Control for Dogs 6 months of age or older]

Effective on indoor and outdoor dogs

[[1][3]4[[6] monthly treatments) [1][3][4][6] Months Supply [24][48] doses

Each tube]applicator] kills fleas & ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks

[Protects for up to [Four/4] Weeks][One month][Four/4 Week [Flea]] Tick][Mosquito] Treatment]

[Aids in Control of Ticks for 3 weeks]

Contains an Insect Growth Regulator (IGR) to kill flea eggs and prevent flea development for

[more than 10 weeks] up to]75 days][2.5 months]

[Starts Killing Fleas and Ticks within 15 minutes]

]Kills 85% of ticks within 48 hours]

[Dual Action kills adult fleas and prevents flea development]

[Breaks Flea Life Cycle for [more than 10 weeks] up to [75 days][2.5 months]

[Controls reinfestation for [more than 10 weeks] up to [75 days][2.5 months]

[Kills fleas, ticks, mosquitoes, flea eggs and flea larvae] [Dual protection (against fleas and ticks)]

Kills the Deer Tick, which may transmit Lyme Disease

Kills and Repels mosquitoes (a major carrier of canine heartworm)

[With [S-Methoprene] Insect Growth Regulator [IGR] to Break Flea Life Cycle]

Convenient, easy to use ACCU-TIP DISPENSER [applicator][tube[

Spreads naturally with dog's movement (skin and hair oils)

[Non-Irritating][New (use for first production only or 6 months)][Formula]

]Water Resistant][Fast Acting]] Long Lasting][Kills Fleas and Ticks by Contact]

]Easy to use] Longer applicator tip for easy application to long-haired dogs

[Fresh][Clean][Scent][Smell]

[Reapply monthly] [Suitable for year-round use][Month] sticker for home calendar

[Satisfaction guaranteed or your money back]

(Front or Back panel)

ACTIVE INGREDIENTS:

Etofenprox (CAS # 80844-07-1) 30.0%

S-Methoprene (CAS # 65733-16-6) 3.6%

Piperonyl Butoxide (CAS # 51-03-6)* 5.0%

OTHER INGREDIENTS: 61.4%

TOTAL 100.0%

*Equivalent to minimum 4.00% butylcarbityl (6-propylpiperonyl ether) and t.00% related compounds

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for [Ingredients and] Additional Precautionary Statements

NET CONTENTS:

One 1.5 cc Applicator [tube] (Small Dogs)/

One 3.0 cc Applicator [tube] (Medium Dogs)

One 6.0 cc Applicator [tube] (Large Dogs)

One 9.0 cc Applicator [tube] (Extra Large Dogs)

EPA Reg. No. 2724-796

EPA Est. No.

RF2042 [CDSO]

IMPORTANT! Intended for Use on Dogs 6 Months of Age or Older

READ ENTIRE LABEL BEFORE EACH USE. USE ONLY ON DOGS. DO NOT USE ON OTHER ANIMALS!

[RF2042]CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.]

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

~~RF2042 [CDSO] prevents flea eggs from developing into adult fleas [more than 10 weeks] for up to [75 days][2.5 months]. RF2042 [CDSO] also kills fleas and ticks for 3 weeks and kills and repels mosquitoes for 3 to 4 weeks.~~

RF2042 [CDSO] works by application directly to the dog's skin, not to the hair. When applying, manually push aside dog's hair to allow direct application to the skin. Do not get this product in dog's eyes or mouth.

[(Note: Application now assumes one applicator per animal per application)]

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [SMALL][MEDIUM] SIZE DOGS

1. Bend at perforation and tear off first applicator [tube]. [
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body.
3. The dog should be standing for easy application. RF2042 [CDSO] should be applied evenly to [two spots](small dogs)[three spots](medium dogs) on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.
4. Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
5. Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month..
6. Discard empty [tube][applicator] as described in Storage and Disposal

[Note: Each package contains sufficient tubes/applicators for [X] applications]

FOR [LARGE][EXTRA LARGE] DOGS

1. Bend at perforation and tear off first applicator [tube]. [(Note – multi-application pack)]
2. Hold applicator [tube][and bend area of plastic at perforation, tear off and discard.] Hold applicator [tube] upright and snap tip back, away from face and body
3. The dog should be standing for easy application. Apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog.

[Alternate Directions for Use for multi-tube application

- 3 The dog should be standing for easy application. Using the first applicator [tube], apply RF2042 [CDSO] evenly to four or five spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the applicator [tube] on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of the solution at any one spot that could cause some of the solution to run off the side of the dog. Using the second applicator [tube], apply as indicated for first applicator [tube] except start application at base of tail and apply on top of the back to the shoulder.
- 4 Do not spread RF2042 [CDSO] by hand over the dog. Although the dog's skin and hair oils will naturally distribute the application over the entire dog, brushing the dog 12-24 hours after application will help to distribute the material over the skin..
- 5 Do not reapply product for 30 days unless re-treatment is required, but not sooner than 8 days after the initial treatment. Do not retreat more than once per month.
- 6 Discard empty [tube][applicator] as described in Storage and Disposal

RF2042 [CDSO] is most effective when used as part of a total flea and tick management program. Use other [Brand Name] products registered for residential area control of these pests in conjunction with this treatment. Monthly treatments are required for optimal control and prevention of fleas.

[The successive feeding activity of fleas on pets may elicit a hypersensitivity skin disorder known as flea allergy dermatitis (FAD). Treatment of pets with RF2042 [CDSO] rapidly kills fleas and may reduce the incidence of this condition.]

[RF2042 [CDSO] is water resistant and remains efficacious following exposure to rainfall or swimming.]

TREATMENT SCHEDULE			
Dosage: 1 applicator every 30 days per dog			
Pet's Name	First Treatment Date	Second Treatment Date (30 Days From 1 st)	Third Treatment Date (30 Days From 2 nd)

Reminder: I purchased RF2042 [CDSO] from: _____ NOTES: _____
Treatment table can be expanded based on package size. (6 months)

STORAGE and DISPOSAL: . **Pesticide Storage:** Store in a cool area away from children and animals. **Disposal:** If empty: Do not reuse container [tube][applicator]. Place in trash or offer for recycling if available. If partially filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

DO NOT USE ON DOGS LESS THAN 6 MONTHS OLD. For external use only. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Repeated exposure to etofenprox can cause skin irritation. Consult a veterinarian before using this product on debilitated, aged, pregnant, nursing, or animals on medication. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur, bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately.

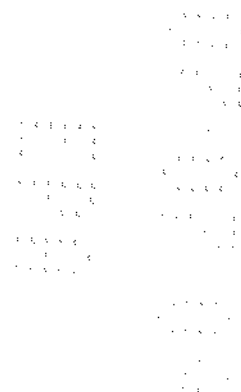
FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after first 5 minutes, then continue rinsing • Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-XXX-XXXX for emergency medical treatment information.	

WARRANTY AND CONDITIONS OF SALE:

Seller warrants that this product conforms to the chemical specifications expressed on the label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, seller's liability for default, breach, or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

In case of emergency or for product information, call 1-800-xxx-xxxx.

Wellmark International
 1501 E. Woodfield Road, 200W
 Schaumburg, Illinois 60173
 [URL]
 Made in USA



NOTIFICATION

JUL 24 2009

United States Environmental Protection Agency
Office of Pesticide Programs (H7505C)
401 M Street SW
Washington, DC 20460

VK
9/13/10

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product
2724-796

Distributor Company Number
270

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)
RF2042 (CDSO)

Distributor Product Name
Adams Flea & Tick Spot On B30 for Toy Dogs

Name and Address of Distributor (Type; include ZIP code)
Farnam Companies, Inc.
P.O. Box 34820
Phoenix, AZ 85067-4820

Read All Conditions Before Signing


1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for ...," distributed by..."; or sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date


Cheryl Purcell
Regulatory Specialist

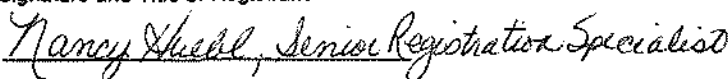
9-3-10

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date


Nancy Wheel, Senior Registration Specialist

September 3, 2010

Confidential Statement of Formula may be entitled to confidential treatment